

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Sakae SATO et al.

Conf. 1832

Application No. 10/531,570

Group 1651

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Examiner S. Saucier

PLASMA PREPARATION OR SERUM PREPARATION AND PROCESS FOR  
PRODUCING THE SAME

DECLARATION

Assistant Commissioner for Patents  
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Sir:

1. I, Tetsuo SATO, a named inventor, am a citizen of Japan and reside at c/o Asahi Kasei Medical Co., Ltd., 1-105 Kanda Jinbocho, Chiyoda-ku, Tokyo, Japan.

2. I am familiar with the above-identified U.S. patent application, its prosecution before the United States Patent and Trademark Office, and the applied references of JP 64-051075 and JP 3-146067

3. In order to demonstrate the patentability of the present invention over the applied art references, I am submitting the following observations.

The present invention has been compared with the applied art by calculating the amount of treated plasma or the time necessary for the treatment based on a membrane area, and found that the present invention is effective in that the time necessary for the treatment is much shorter.

In the Example of JP 64-51075, ten thousand hollow fibers of 20 cm length for removing virus were bundled and formed into a module. There is no disclosure of a membrane area or an inner diameter of the module, but the inner diameter of the hollow fiber is disclosed to be 200-800  $\mu\text{m}$  (page 4, right lower column, line 7). Based on this inner diameter, a membrane area of the module is calculated to be 1.3-5.0  $\text{m}^2$ .

Blood was introduced from a blood-inlet at a speed of 70 mL/min and plasma was made to run into a plasma flow channel at a speed of 20 mL/min, in a virus-removing device where the above module is used (Figure 1), thus treating 3 L of blood (page 8, left upper column, lines 1-3). Generally speaking about 70% of blood is plasma, so it is assumed that it took 105 minutes to treat 2.1 L of plasma. (The average pore size of the hollow fiber is disclosed to be 35  $\mu\text{m}$ , which should read as 35 nm, considering the size of virus.)

On the other hand in the present invention, it took 30 minutes to filter 250 mL (0.25 L) of plasma by a virus-removing

membrane which has an average pore size of 35 nm and a membrane area of 0.06 m<sup>2</sup>.

As shown in below table, about 2.6 - 9.9 times the plasma can be treated in the same treatment time by the present method. Further for treating the same amount of plasma, the treatment time is shortened to 1/9 to 1/35 compared to that of the reference, 105 minutes.

	JP 64-51075	Present invention	A: <i>Assuming membrane area of the present invention to be same with that of the reference</i>	B: <i>Further assuming the amount of treated plasma to be same with that of the reference</i>
Amount of plasma (L)	2.1	0.25	5.5 - 20.8 2.6 to 9.9 times of plasma (compared to 2.1 L of reference) can be treated in 30 minutes.	2.1
Membrane area (m <sup>2</sup> )	1.3 - 5.0	0.06	1.3 - 5.0	1.3 - 5.0
Treatment time (min)	105	30	30	12 - 13 Treatment time was shortened to 1/9 to 1/35 (compared to 105 minutes of reference) to treat same amount of plasma.

Notes: The amount of treated plasma was assumed to be in proportion to a membrane area (A in the table). Also the

amount of treated plasma was assumed to be in proportion to treatment time (B in the table).

These above observations show unexpected results and the criticality of the steps of the present invention.

4. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date April 2, 2009

  
Tetsuo SATO